

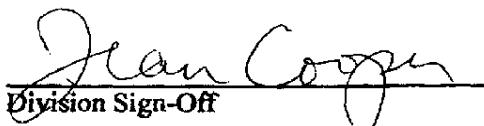
INTENDED USE

510(k) Number: K030477

Device Name: diaDexus PLAC™ test

Indications for Use:

The diaDexus PLAC™ test is an enzyme immunoassay for the quantitative determination of Lp-PLA2 (lipoprotein-associated phospholipase A2) in human plasma, to be used in conjunction with clinical evaluation and patient risk assessment as an aid in predicting risk for coronary heart disease.

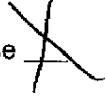

Division Sign-Off

Office of In Vitro Diagnostic Device
Evaluation and Safety

510(k) K030477

(PLEASE DO NOT WRITE BELOW THIS LINE- CONTINUE ON ANOTHER PAGE AS
NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use 

OR

Over-the-Counter Use

PM3006731403